

# ***Field Safety Study of PUREVAX<sup>®</sup> Recombinant Leukemia administered to cats with the VET JET<sup>™</sup> transdermal vaccination system***

## **KEY POINTS**

- The results of several field studies showed that PUREVAX Recombinant Leukemia vaccine administered with the VET JET transdermal vaccination system was SAFE for use in cats as young as 8-weeks of age.
- In these closely monitored studies, over 1,500 doses of PUREVAX Recombinant Leukemia vaccine were administered with the VET JET transdermal vaccination system to more than 750 cats with only isolated and transient incidences of mild lethargy, hyperthemia, or pain upon palpation of injection site (<2.0%).

**Zack Mills, DVM**  
**Merial Veterinary Services**

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## **Introduction**

The objective of these studies was to evaluate the safety of the PUREVAX Recombinant Leukemia vaccine administered with the VET JET transdermal vaccination system under field conditions.

## **Methods**

Seven hundred seventy-eight (778) privately-owned cats, of which 224 were minimum age animals ranging from 8-10 weeks of age, from three different geographical regions in the U.S., were vaccinated by private practitioners with PUREVAX Recombinant Leukemia vaccine using the VET JET transdermal vaccination system.

A physical examination was performed on every cat prior to the first vaccination and included, but was not limited to, temperature, pulse, and respiration. In most cases, a blood sample was collected and FeLV p27 antigenemia status was determined using a commercially available in-clinic ELISA test prior to vaccination.

The cats were taken to the clinics as part of a routine veterinary visit and many received other vaccinations, treatments for internal or external parasites as needed. Medications during the 1-hour post-vaccination observation period were kept to a minimum.

Two single doses of 0.25 mL each were administered at approximately a 21-day interval using the VET JET transdermal vaccination system. The vaccine was given transdermally in the middle lateral thigh, caudal to the femur over semimembranosus and semitendinosus muscle groups.

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## **MERIAL STUDY REVIEW**

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## Vaccination and Monitoring

Day 0: Initial vaccination: Following vaccination, veterinarians observed the cats for one (1) hour post-vaccination

Day 10 to 21: Owners contacted to obtain animal health information and owner observations

Day 18 to 21: Second vaccination with 1-hour post-vaccination veterinarian observation

Day 35 to 42: Final clinical observations by veterinarian or obtained through owner contact

## Observation Methods

For one (1) hour after vaccination with PUREVAX Recombinant Leukemia, cats were observed for any potential severe systemic adverse reactions.

*Severe systemic adverse reactions defined as those having a serious impact on the health of the animal and requiring immediate veterinary intervention, including, but not limited to, anaphylactic shock, hyperthermia, and vomiting resulting in clinical signs requiring corrective therapy.*

Cat owners observed vaccinated animals daily for 14-days post-vaccination for signs of systemic illness and local injection site reactions, such as lethargy, vomiting and heat, pain, swelling, or abscess formation at injection site.

In addition, veterinarians made a visual inspection of the site of vaccination in all animals presented for second vaccination. The visual inspection/observation was for heat, pain, abscess, and persistent nodule. Nodules were further classified for severity on the basis of size. Many of the minimum age animals were presented again approximately 14 days following the second vaccination with PUREVAX Recombinant Leukemia. About  $\frac{3}{4}$  of the minimum age cats were examined and results recorded for any vaccination site issues.

## Results

Table 1.

AGE	1st VACCINATION	2nd VACCINATION	TOTAL DOSES
8-10 weeks of age	224	222	446
>10 weeks of age	554	537	1,091
Total	778 <sup>a</sup>	759	1,537

<sup>a</sup> Four cats were removed from the study prior to Day 14 observation period for reasons unrelated to administration of vaccine.

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## One (1) hour Post-Vaccination Observations (Veterinarian)

No cats had any severe systemic adverse reactions that required veterinary intervention. Seven cats (<0.5% of vaccinations) had immediate post-vaccinal pain or discomfort on palpation and 4 cats (<0.3% of vaccinations) had acute lethargy.

## Owner Observations (up to 14-days post-vaccination)

The only owner-reported observations were mild lethargy and pain on palpation at the injection site. There were 13 reports of lethargy (<0.9% of vaccinations) and 5 reports of injection site pain or discomfort on palpation (<0.4% of vaccinations)

One cat on the day following vaccination was presented to the veterinarian with lethargy, inappetence, and pain on palpation of the injection site. The cat was treated with 1 dose of a NSAID and the cat was normal within 2 hours.

## Injection Site Observations

Veterinarians examining cats at the time of the second vaccination reported no nodule formation at any of the initial 759 vaccination sites. Additionally, 158 of the minimum age vaccinates were returned to the veterinarian approximately 14 days post-second vaccination and no nodules were observed in any of these cats. One owner reported a small "lump" at the site, which resolved within 3 days post-vaccination without treatment.

## **Conclusion**

The non-adjuvanted PUREVAX Recombinant Leukemia vaccine administered in a 0.25 mL dose with the VET JET transdermal vaccination system by different administrators in different regions of the U.S. has demonstrated an EXCELLENT SAFETY profile for use in various ages and breeds of cats as young as 8-weeks of age.

Only isolated and transient incidence of mild hyperthermia, lethargy, and pain at the injection-site upon palpation were reported by veterinarians and pet owners during post-vaccination observation, none were inconsistent with what is expected following vaccination in cats. The lack of nodule formation from any of the 1537 vaccine doses emphasizes one key benefit of a non-adjuvanted vaccine - no chronic inflammation.

The excellent safety profile documented in this field study, along with a separate viral challenge study, demonstrating 100% efficacy in preventing persistent viremia when 90% of controls became persistently viremic, illustrates why PUREVAX Recombinant Leukemia should be the veterinarian's vaccine of choice.

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### **References:**

<sup>1</sup>Data on file

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